PCT/JP2003/011548

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

511549

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
Y0352PCT-698		
International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/JP2003/011548	10 September 2003 (10.09.2003)	11 September 2002 (11.09.2002)
International Patent Classification (IPC) or national classification and IPC C12Q 1/02, 1/66, C07K 14/72, G01N 33/15, 33/50, A61K 45/00, A61P 3/10		
Applicant YAMANOUCHI PHARMACEUTICAL CO., LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07 November 2003 (07.11.2003)	23 March 2004 (23.03.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

Form PCT/IPEA/409 (cover sheet) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/011548

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 8-11

because:

☒ the said international application, or the said claims Nos. 10
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The above claim relate to "methods for treatment of the human or animal body by surgery or therapy" in RCT Rule 67.1 (iv).

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 8-11
are so unclear that no meaningful opinion could be formed *(specify)*:

The specification describes only a few specific examples of "substances to activate polypeptides" described in claims 9-11. Accordingly, claims 9-11 are not adequately supported, or disclosed, by the specification. Even with the common technical knowledge prevailing at the time of filing taken into consideration, it is not at all clear what substances other than the disclosed ones fall within those substances. It is, therefore, impossible to make a meaningful search on the subject matters of the said claims. This applies to the subject matter of claim 8 because it involves a process of producing preparations of "substances to activate polypeptides."

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 8-11.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	6-7	YES
	Claims	1-5	NO
Inventive step (IS)	Claims		YES
	Claims	1-7	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims		NO

2. Citations and explanations

Document 1: WO, 02-44362, A1 (Yamanouchi Pharmaceutical Co., Ltd.), 6 June, 2002 (06.06.02)
Document 2: Biochemical Pharmacology, August 2002, Vol. 64, No. 4, pages 689-697

Claims 1-5

The subject matters of claims 1-5 do not appear to be novel in view of document 1.

Document 1 describes a method of, and a tool for, screening substances to promote the secretion of insulin that consist of the same polypeptide as that of the present application. The substances that are screened for are "substances to promote the production of insulin" in the subject matters of claims 1-5; on the other hand, "substances to promote the secretion of insulin" in the invention described in document 1, and the former is different from the latter in that respect. However, because the polypeptide is the same, even though screening methods for agents to promote insulin production and/or increase the insulin content are not disclosed, the former and the latter are not different in their structure as "screen tools" that consist of the said polypeptide.

The subject matters of claims 1-7 do not appear to involve an inventive step in view of documents 1 and 2.

Document 2 describes that glucagons-like peptide GLP-1 promotes both the "secretion of insulin" and the "expression of insulin genes." Thus, a person skilled in the art could have easily conceived of the idea of applying the invention described in document 1 that relates to the screening for substances to promote the secretion of insulin, to the screening for substances to promote the production of insulin, in the expectation that substances to promote the secretion of insulin can promote the expression of insulin genes, in other words, the production of insulin.

The applicant explains in its written reply that the "promotion of secretion of insulin" and the "promotion of production of insulin" are different actions based on different mechanisms, and there are substances promoting the secretion of insulin that inhibit the production of insulin, and so a person skilled in the art would not expect that substances promoting the secretion of insulin would promote the production of insulin. Even though there are such substances, however, it is clear, as described in document 2, that there could exist substances to promote both the "secretion of insulin" and the "production of insulin," and so a person skilled in the art could have easily conceived of the idea of using the invention of document 1 for the screening for substances to promote the production of insulin in the expectation that the substances described in document 1 would promote not only the "secretion of insulin" but also the "production of insulin."